DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 17, 1999, 9 a.m. to 5:30 p.m.

Location: Corporate Bldg., conference rm. 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Robert J. Doyle, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12526. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss bone strength assessment, with a focus on the use of gender-specific and race-specific data bases in assessing fracture risk and their applicability to bone densitometry and sonometry device labeling.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 6, 1999. Oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m., and for an additional 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 6, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On May 17, 1999, from 12:15 p.m. to 12:45 p.m., the meeting will be closed to the public to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) relating to present and future agency issues.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 23, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0280]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. This is necessary to prevent public harm. Last year, the volatile nature of the Medicare market created a critical need for plan-specific Medigap data. The unanticipated event of numerous health plans terminating their Medicare contract surprised everyone. The plan-specific Medigap information was, and continues to be, essential for beneficiaries who are in health plans that terminate their Medicare contract. Last year, when the volume of health plan terminations occurred, no one had national plan-specific Medigap data to provide to beneficiaries affected by the mass terminations. By providing this plan-specific Medigap data, beneficiaries will be able to make a more realistic comparison of their costs and benefits under each option available to them. This will prevent harm to the beneficiaries caught in a difficult situation with a relatively short period of time to make an informed decision. We cannot reasonably comply with the normal clearance procedures because we must have the necessary data collected and able to be published in July, when Medicare health plan terminations are announced.

HCFA is requesting OMB review and approval of this collection within 11 working days, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below within 10 working days. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Request: New collection.

Title of Information Collection: Medigap Compare.

HCFA Form Number: HCFA–R–0280 (OMB approval #: 0938–NEW).

Use: HCFA will collect plan-specific Medigap data, including but not limited to premiums charged and additional benefits offered, from each insurer offering Medigap plans. The data collection will occur electronically. The data will be provided on www.medicare.gov to assist beneficiaries in obtaining accurate information on all their health care coverage options.

Frequency: Annually, and semi-annually if needed.

Affected Public: Business or other for-profit, Federal Government, State, Local,